

**REMARKS**

Claims 1-2, 4-7, 11, 15-19, 23 and 29 are pending in this application.

Claim 16 was objected to because hybridization was misspelled.. The claim has been amended to correct this error.

**Rejections Under 35 U.S.C. §112**

Claims 17 and 29 were rejected under 35 U.S.C. § 112, first paragraph as not enabled because they were directed to a medicament. Applicant's have amended the claims. The claims are now directed to a composition. Applicants respectfully submit that the claims are now compliant with the §112, ¶1 enablement requirement.

Claims 1, 2, 4, 5, 18 and 19 were rejected under 35 U.S.C. § 112, first paragraph, as non-enabled. Applicants traverse this objection. Examiner asserts that while the application enables the invention in the Rama 37 cell line, it is not enabled in other cell lines because "applicants have not described any other cell line that produces benign and non-metastasizing tumor when injected in a syngeneic animal and which when transfected with another DNA will produce metastasis."

In a supplemental IDS, Applicant provided three references describing a "cell line that produces benign and non-metastasizing tumor when injected in a syngeneic animal and which when transfected with another DNA will produce metastasis." In Vousden, et.al. Enhanced Spontaneous Metastasis of Mouse Carcinoma Cells Transfected With An Activated c-Ha-ras-1 Gene, a mouse adenocarcinoma cell line is described that produces benign non-metastasizing tumors when injected into a syngeneic animal(page 425). Once the cells have been transfected with ras, the line becomes metastatic (Page 426-429). Two other references, Radler-Pohl, et.al. And Thorgeirsson et. al. describe similar cell lines- a mouse bladder epithelial cell line and a NIH/3T3 cell line, respectively, that exhibit the same characteristics. These references

demonstrate that the method of producing benign, non-metastasizing tumors in animals was well known. Withdrawal of this rejection is respectfully requested.

Claims 1, 2, 4, 5, 18 and 19 were rejected under 35 U.S.C. § 112, first paragraph, lacking adequate written description. Applicants traverse this objection. Examiner asserts that the specification teaches only a Rama 37 cell line species and no other species of the genus(a cell line). As discussed above, at the time of the application, numerous cell lines that produce benign and non-metastasizing tumor when injected in a syngeneic animal and which when transfected with another DNA will produce metastasis, were well known. Withdrawal of this rejection is respectfully requested.

Claim 16 was rejected as non-enabling because, the Examiner asserts, the specification provides no guidance as to how a probe would be designed. Applicants traverse this rejection. First, the design of probes to desired specificity was well known in the art at the time of this application. Second, in contrast to Examiner's assertions, the specification does provide guidance. On page 19 of the Application, referring to probes, states: "By specific is meant hybridises to any target DNA under suitable salt and temperature conditions to allow detection of identical or related DNA molecules." Thus, in contrast to Examiner's assertions, guidance was provided. With the information provided in the application, one of skill in the art could easily design a suitable probe for the claimed kit. Removal of this rejection is respectfully requested.

Claims 1, 2, 4-6, 15, 17-19, 23 and 29 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants have amended claim 1 to insert an antecedent basis for "the transformed cells." This amendment clarifies the claims and in no way narrows the scope of the claims. Removal of this rejection is respectfully requested.

#### **Rejections Under 35 U.S.C. §102**

Claims 15 and 23 were rejected under 35 U.S.C. § 102(e) as being anticipated by Sazaki et al. Sazaki et al. teach a DNA sequence of almost 7,000 bases of which only 17


bases align with 17 bases from the nearly 1100 bases disclosed in the present application. Applicants have amended the claim to require that any probe be less than 6000 bp in length. Since Sazaki et. al. teach a sequence of nearly 7000 base pairs, it does not anticipate. Removal of this rejection is respectfully requested.

Applicants have made a genuine effort to respond to the Examiner's rejections in advancing the prosecution of this case. Applicants believe all formal and substantive requirements for patentability have been met and that this case is in condition for allowance, which action is respectfully requested.

The Examiner is requested to telephone the undersigned to discuss resolution of any issues necessary to place this case in condition for allowance. Please charge any additional fees or credit any overpayment s as the result of the filing of this paper to our Deposit Account No. 02-3978.

Respectfully submitted,

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